



U.S. FOOD & DRUG
ADMINISTRATION

Reference: FOI # 2018-9519

January 31, 2019

Claire Tighe
MuckRock News DEPT MR 63573411A
Highland Ave.
Somerville, MA 02144

Via email: 63573-94682214@requests.muckrock.com

Dear Claire Tighe,

The attached record(s) are being provided by the Office of Regulatory Affairs (ORA), Division of Information Disclosure Policy – **San Francisco Queue**, in response to your request **2018-9519 dated 11/26/2018** for record(s) from the Food and Drug Administration pursuant to the Freedom of Information Act regarding:

Subject:	BAYER INSPECTION RECS
Orig. Subject:	See attached letter for request.

Your request is granted in part.

After a thorough review of the responsive records, we have determined that portions of the documents are exempt from disclosure under FOIA exemptions (b)(4), (b)(5), (b)(6) and (b)(7) of the FOIA 5 U.S.C. § 552, as amended and delineated below:

- Exemption (b)(4) permits the withholding of “trade secrets” (TS) and “commercial confidential information” (CCI). Disclosure of this information would impair the government’s ability to obtain necessary information in the future and cause substantial harm to the competitive position of the person from whom the information was obtained. Under the balancing test of this exemption, we are withholding all proprietary information identified as TS and CCI.
- Exemption (b)(5) permits the withholding of inter-agency or intra-agency communications records which are part of the deliberative process and pre-decisional. Disclosure of such material could inhibit the open and candid expression of opinions and diminish the quality of the decision-making process.

U.S. Food and Drug Administration
5630 Fishers Lane, Room 1035
Rockville, MD 20857
www.fda.gov

- Exemption (b)(6) permits the withholding of information which, if released, would constitute a clearly unwarranted invasion of personal privacy. In this case, it was determined that there is no countervailing public interest qualifying under the standard set forth, under exemption (b)(6), to release the personal identifying information of certain third parties.
- Exemption (b)(7) protects from disclosure "records or information compiled for law enforcement purposes, but only to the extent that the production of such law enforcement records or information (A) could reasonably be expected to interfere with enforcement proceedings, (B) would deprive a person of a right to a fair trial or an impartial adjudication, (C) could reasonably be expected to constitute an unwarranted invasion of personal privacy, (D) could reasonably be expected to disclose the identity of a confidential source, including a State, local, or foreign agency or authority or any private institution which furnished information on a confidential basis, and, in the case of a record or information compiled by a criminal law enforcement authority in the course of a criminal investigation, or by an agency conducting a lawful national security intelligence investigation, information furnished by a confidential source, (E) would disclose techniques and procedures for law enforcement investigations or prosecutions, or would disclose guidelines for law enforcement investigations or prosecutions if such disclosure could reasonably be expected to risk circumvention of the law, or (F) could reasonably be expected to endanger the life or physical safety of any individual.

The Division of Information Disclosure Policy – **San Francisco Queue** considers your request closed. If you have any questions about this response, you may contact me at jason.schilling@fda.hhs.gov or 214-253-5262.

You have the right to appeal this determination. By filing an appeal, you preserve your rights under FOIA and give the agency a chance to review and reconsider your request and the agency's decision.

Your appeal must be mailed within 90 days from the date of this response, to:

Agency Chief FOIA Officer
U.S. Department of Health and Human Services
Office of the Assistant Secretary for Public Affairs
Room 729H
200 Independence Avenue, S.W.
Washington, DC 20201
E-mail: FOIARequest@PSC.hhs.gov.

Please clearly mark both the envelope and your letter "Freedom of Information Act Appeal."

If you would like to discuss our response before filing an appeal to attempt to resolve your dispute without going through the appeals process, please contact me at jason.schilling@fda.hhs.gov or 214-253-5262. You may also contact the FDA Public Liaison for assistance at:

Office of the Executive Secretariat
U.S. Food & Drug Administration
5630 Fishers Lane, Room 1050
Rockville, MD 20857
E-mail: FDAFOIA@fda.hhs.gov

If you are unable to resolve your FOIA dispute through our FOIA Public Liaison, the Office of Government Information Services (OGIS), the Federal FOIA Ombudsman's office, offers mediation services to help resolve disputes between FOIA requesters and Federal agencies. The contact information for OGIS is:

Office of Government Information Services
National Archives and Records Administration
8601 Adelphi Road—OGIS
College Park, MD 20740-6001
Telephone: 202-741-5770
Toll-Free: 1-877-684-6448
E-mail: ogis@nara.gov

Please do not submit payment until you receive an invoice. The following charges for this request to date may be included in a monthly invoice:

FOI request fees: <https://www.fda.gov/RegulatoryInformation/FOI/FOIAFees/default.htm>
Your estimated fees will be:

Total: \$0.00

Sincerely,

Jason Schilling, MBA
Government Information Specialist
FOIA Branch 2
Division of Information Disclosure
Office of Strategic Planning and Operational Policy
Office of Regulatory Affairs

Enclosure(s):

1. SAN queue, Bayer Healthcare, Milpitas, CA, 482s, 2008-2015 (21 pgs)
2. SAN queue, Bayer Healthcare, Milpitas, CA, EIR, 06-30-2015 (12 pgs)
3. SAN queue, Conceptus, Mountain View, CA, 483, 01-06-2011 (3 pgs)
4. SAN queue, Conceptus, Mountain View, CA, EIR endorsements 2002-2015 (6 pgs)
5. SAN queue, Conceptus, Mountain View, CA, EIR, 01-06-2011 (17 pgs)
6. SAN queue, Conceptus, Mountain View, CA, EIR, 06-26-2013 (3 pgs)
7. SAN queue, Conceptus, Mountain View, CA, FDA memo, 03-01-2011 (2 pgs)
8. SAN queue, Conceptus, Mountain View, CA, Firm 483 response ltr, 01-20-2011 (6 pgs)
9. SAN queue, Conceptus, Mountain View, CA, FMD-145 letter to firm, 11-21-2013 (1 pg)
10. SAN queue, Conceptus, Mountain View, CA, Letter to firm, no date (1 pg)